

Remarks/Arguments

By virtue of this paper, claims 1, 14, 18, 27, and 28 are sought to be amended, claims 4-6, 9-13, 16-17, 19,20, 22,23 , 25,26, 29 and 30 are sought to be canceled, and claims 31-32 are withdrawn where claim 31 is sought to be withdrawn but currently amended. . The amendments are believed not to introduce new matter, and their entry is respectfully requested. The cancellations and amendments are made without prejudice or disclaimer. Claims 1, 2, 3, 7,8, 14,15, 18, 21, 24 , 27,28, 31 and 32 are respectfully presented for consideration further in view of the below remarks.

Specification

A substitute abstract, one marked version showing deleted material as crossed out lines and also a clean version of substitute abstract is submitted herewith. The substitute abstract contains no new matter. Applicant respectfully requests Examiner to enter substitute abstract.

Elections/ Restriction

Response to Election/Restriction Requirements, Applicant elects Group I with Claims 1-3,7-8,14-15,18,21,24,27-28 drawn on implant assembly without traverse. Claims of Elected Group I, 1, 14,18,27,28 are amended to further describe applicant's invention. Claim of Group II 31,32 are withdrawn and presently amended to further clarify applicant's invention and to include all the limitations of generic claim 1 to allow rejoinder of these claims. Amendments are fully supported by specification and figures as originally filed. No new matter is believed or intended to be introduced by these amendments. As claims of Group II, 31, 32 are withdrawn and presently amended (See MPEP 714, permitting amendments to withdrawn claims) to include all the limitations of elected generic claim 1, applicant respectfully respect withdrawal of Election/ Restriction requirements and rejoin the claims of Group II 31 and 32 .

Claim Rejections - 35 U.S.C. § 112

On page 4 of Non Final Office Action mailed on June, 03, 2009 , the Examiner rejected Claims **1-3,7-8,14-15,18,21,24,27** under 35 U.S.C. § 112 , second paragraph . The Examiner is thanked for continuing examination, and thereby furthering prosecution. Applicant has amended said claims so that there is proper antecedent basis and to further defines Applicant's invention. No new matter has been introduced and the amended claims, which are believed to overcome the rejection under 35 U.S.C. § 112, second paragraph.

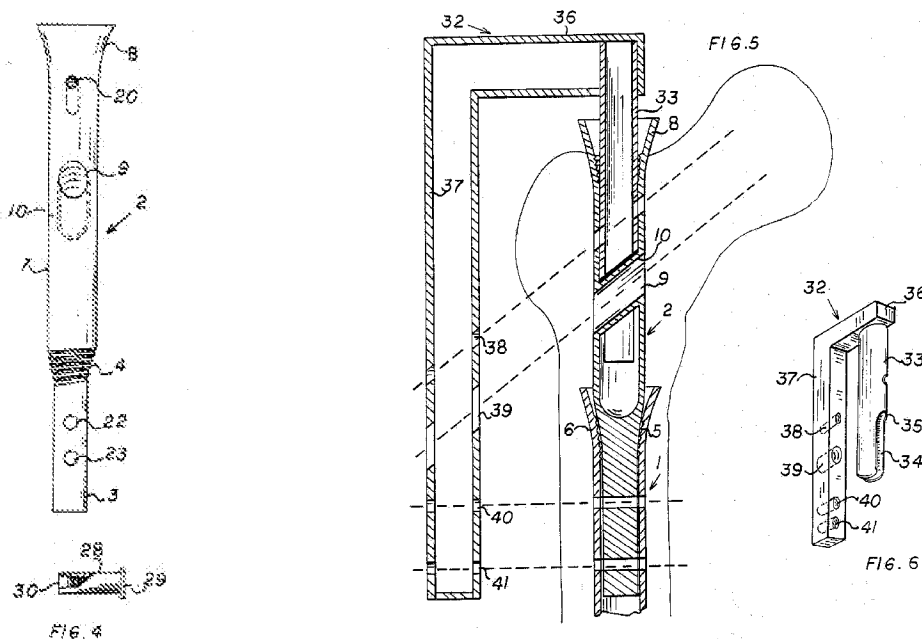
Claim Rejections - 35 U.S.C. § 102

Claim 1 is rejected under **35 U.S.C. 102(b)** as being anticipated by Marino (US 4,733,654.) .Applicant respectfully requests entry of amended independent Claim 1. Claim 1 has been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification at, e.g.paragraphs **[[0005],[0016],[00028],[00040],[00086],[00087],[00096], Figs.9,28and31.** Applicant submits that "Marino" (US 4,733,654) does not suggest or teach or disclose each and every feature or element of amended claim 1. Kit of combinations disclosed by Marino comprises a standard routine intramedullary nail 1 like Kuntscher couples with extension 2 where extension 2, also illustrated in FIG. 2, has a distal tip 3 with conical threads 4 dimensioned to match the female thread 5 in the proximal head 6 of the nail 1 (Col. 2 ll 30-50, Figs 1, 2). Thus intramedullary nail disclosed by Marino is two piece nail with joint with thread attachment. This threaded joint weakens the assembly by creating stress riser at junction and there are all chances of opening up of joint during rotation. Marino further discloses "The distal tip 3 of the extension 2 is also drilled orthogonally to form two additional 'bores 22, 23 which are in line with symmetrical bores 24 and 25 in the proximal end of the nail 1. Threaded pins 26 and 27 engage said bores in order to stabilize the proximal end of the nail 1. For further stability the side plate 19 is captured at its lower end 5 through bores 31 by pins 26 and 27 (Marino Col 2 line 67 – Col 3 line 6). Marino further discloses and recommends to install a grommet 28 into lined up bores 23 and 25 as well as bores 22 and 24 to immobilize extension member 20 within the nail member 1 in order to prevent rotation in between nail 1 and extension member 2 (Marino Col 3 line 43-45) , so it seems that Marino nail assembly has too many joints and that makes the assembly weaker and joining these elements will certainly hamper accuracy and precision while targeting with the help of drill guide. Applicants discloses structurally a unitary- one piece intramedullary nail to avoid these drawbacks.

Marino discloses a first bore 9 surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19 (Marino Col 2 line 47-50). This type of arrangement as taught by Marino where barrel angularly joined with side plate 19 placed through bore 9 with sleeve 10 in extension member 2 requires large opening-bore in extension member 2 leading to further weakening of nail walls and to accommodate larger diameter hole –

diameter of extension member 2 has to be substantially large which will require more reaming of bone tissue and loss of bone near fracture area, hampering healing of fracture (Emphasis added), which is contrary to Applicant's disclosure. Marino describes structure of a first bore 9 (Proximal holes) surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19. Applicant discloses structure of proximal holes in Intramedullary Nail without any tubular sleeve surrounding within the hole. Marino further discloses second but smaller and unsleeved bore 20 is drilled to accommodate smaller pin 21 through the upper end of extension 2 at the same angle and parallel to the first bore 9 (Marino Col 2. Line 62-66). Marino further discloses and illustrates in Fig 5 and Fig 6 (as shown below) a drilling guide 32 adapted for use with extension member 2 comprising guide member 37 with plurality of bores 38 through 41 which are in line with bores 20,9 and bore 22,23 and 24,25 of extension member 2 and nail 1. The positioning leg 33 has bore 38 corresponding to bore 20 in the extension. Marino further discloses drilling guide 32 comprises a tubular positioning leg 33 shaped and dimensioned to engage into the proximal end 8 of the extension 2. It should be noted that the positioning leg 33 is not threaded but fits snugly into the extension 2. (Marino Col 3. line 15-22) A bifurcated lower tip 34 engages the sleeve 10 with the upper end 35 of the forked tip 34 coming to rest against the upper edge of the sleeve 10. In that position any rotational movement of the guide 32 in relation to the extension 2 is prevented. Applicant discloses structure of connecting end of targeting device and connecting end of intramedullary nail coupled or mounted by threaded connecting bolt for better fitting for accuracy of targeting jig.

Fig. 2



Applicant points out that as disclosed by Marino (Fig. 1,5 and 6) positioning leg 33 is also drilled with bore 38 corresponding to the position of bore 20 in the extension and the second pin 21, looking to Fig 2, 5 and 6 after targeting bore 20 in extension member 2 through bore 38 in positioning leg 33 and fixing it with suitable anchor or screw , bifurcate arms of positioning leg 33 will be firmly fixed with extension member and will not allow disengagement of targeting jig from extension member after surgery is complete or one has to engage screw or anchor through bore 20 of extension 2 drilling bone free hand without targeting guide which leads to invasion to patient failing the purpose of surgery. Applicant further points out that Marino discloses structure of Guide arm 37 having a) proximal bores 38 and 39 for corresponding holes 20 and 9 in extension member 2 and b) distal bores 40 and 41 for corresponding holes 22, 23 in extension member 2 , bores 24 ,25 in proximal part of nail member 1 and holes 31 in side plate 19, where proximal bores 38 and 39 and distal bores 40 and 41 are in same plane or parallel plane (Fig. 5 and 6.) Applicant points out that in present application structure and construction of proximal holes 38 of targeting device 41 and distal holes 40 of targeting device 41 are in different plane and plane of center of proximal holes 38 and plane of center of distal holes 40 are intersecting with each other (Present Application Fig.9, 28, 31). Marino discloses extension member 2 having proximal bores one larger 9 and one smaller 20 and distal bores 22 and 23 and Nail member 1 joining with extension member 2 is having proximal holes 24 and 25, where proximal bores 9 and 20 and distal bores 22 and 23 with bore 24 and 25 are in same plane or parallel plane (Fig. 2 Marino). Applicant points out that structure and construction of proximal hole 37 in Intramedullary Nail 42 and distal holes 39 in Intramedullary Nail 42 are in different plane and plane of center of proximal holes and plane of center of distal holes are intersecting with each other (Present Application Fig.9, 28, 31). Accordingly, Marino does not teach or describe, expressly or inherently, each and every element as set forth in amended claim 1 nor does Marino have elements arranged as required by this amended claim 1. As such, Marino does not anticipate or render obvious independent claim 1. Applicant respectfully requests entry and allowance of Claim 1.

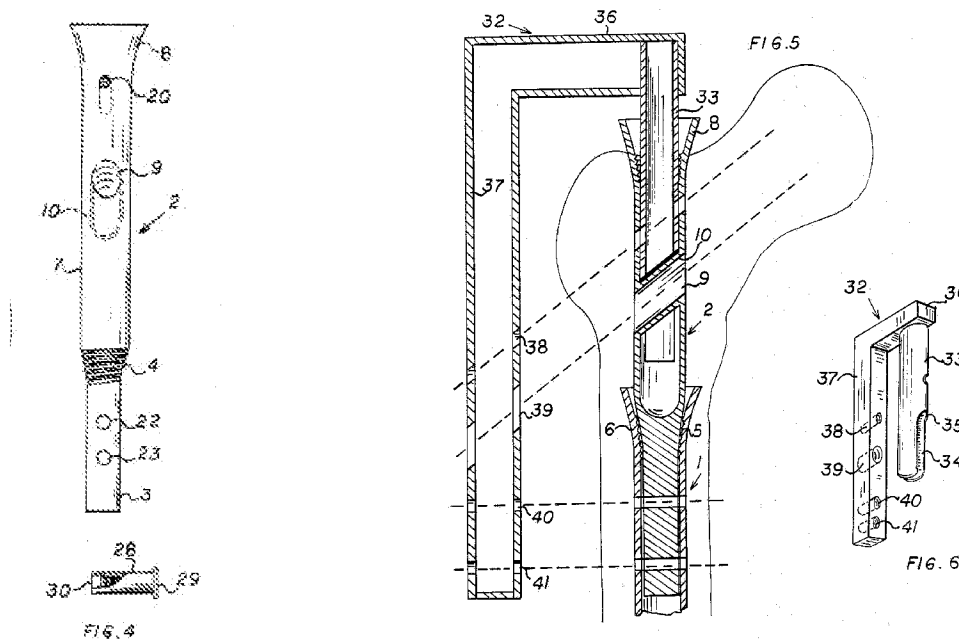
Claim Rejections Under 35 U.S.C. § 103

Claim 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654 in view of Judet et al US 5,591,168 and Engelhardt et al US 4,805,607

Applicant respectfully requests entry of amended dependent Claim 27 and Independent claim 28. Independent Claim 1, dependent Claim 27 and Independent claim 28 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g., paragraphs [[0005], [0016], [[0024] [00028], ., [00036] [00040], ., [00048] [00086], [00087], ., [00089], [00092], [00093] [00096], Figs. 3, 9, 15, 21, 24, 25, 28, 30 and 31. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the according to amended claim 1, 27, 28 and other claims, present invention is constructed structurally different from device of Marino, device of Judet or Engelhardt and it is used in an entirely different manner, thereby overcoming drawbacks in the Kit and method of Marino, Device of Judet and Engelhardt et al either singly or in combination, as well as many similar devices known in the prior art of record. Kit of combinations disclosed by Marino comprises a standard routine intramedullary nail 1 like Kuntscher couples with extension 2 where extension 2, also illustrated in FIG. 2, has a distal tip 3 with conical threads 4 dimensioned to match the female thread 5 in the proximal head 6 of the nail 1 (Col. 2 ll 30-50, Figs 1, 2). Thus intramedullary nail disclosed by Marino is two piece nail with joint with thread attachment. This threaded joint weakens the assembly by creating stress riser at junction and there are all chances of opening up of joint during rotation. Marino further discloses "The distal tip 3 of the extension 2 is also drilled orthogonally to form two additional 'bores 22, 23 which are in line with symmetrical bores 24 and 25 in the proximal end of the nail 1. Threaded pins 26 and 27 engage said bores in order to stabilize the proximal end of the nail 1. For further stability the side plate 19 is captured at its lower end 5 through bores 31 by pins 26 and 27 (Marino Col 2 line 67 – Col 3 line 6) . Marino further discloses and recommends to install a grommet 28 into lined up bores 23 and 25 as well as bores 22 and 24 to immobilize extension member 20 within the nail member 1 in order to prevent rotation in between nail 1 and extension member 2 (Marino Col 3 line 43-45), so it seems that Marino nail assembly has too many joints and that makes the assembly weaker and joining these elements may hamper accuracy and precision while targeting with the help of drill guide. Applicants discloses structurally a unitary- one piece intramedullary nail to avoid these drawbacks.

Marino discloses a first bore 9 surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11

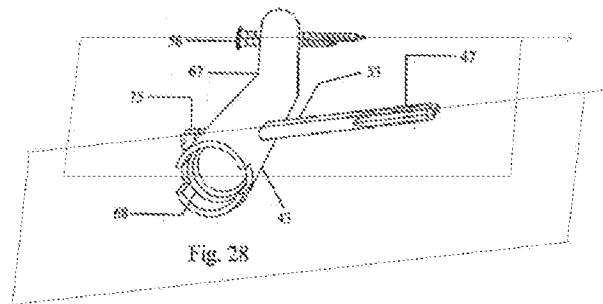
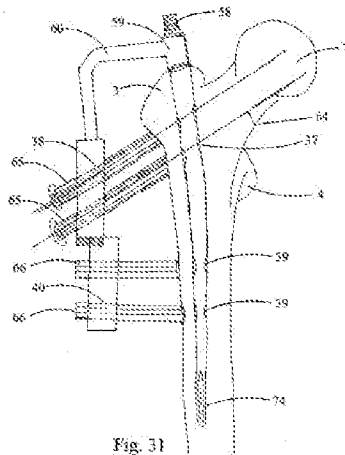
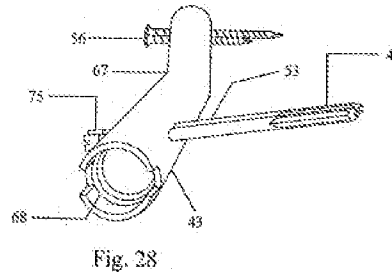
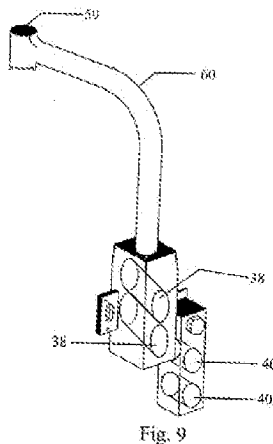
with its engagement with barrel of side plate 19 (Marino Col 2 line 47-50). This type of arrangement as taught by Marino where barrel angularly joined with side plate 19 placed through bore 9 with sleeve 10 in extension member 2 requires large opening-bore in extension member 2 leading to further weakening of nail walls and to accommodate larger diameter hole – diameter of extension member 2 has to be substantially large which will require more reaming of bone tissue and loss of bone near fracture area, hampering healing of fracture (Emphasis added), which is contrary to Applicant's disclosure . Marino describes structure of a first bore 9 (Proximal holes) surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19. Applicant discloses structure of proximal holes in Intramedullary Nail without any tubular sleeve surrounding within the hole. Marino further discloses second but smaller and unsleeved bore 20 is drilled to accommodate smaller pin 21 through the upper end of extension 2 at the same angle and parallel to the first bore 9 (Marino Col 2. Line 62-66). Marino further discloses and illustrates in Fig 5 and Fig 6 (as shown below) a drilling guide 32 adapted for use with extension member 2 comprising guide member 37 with plurality of bores 38 through 41 which are in line with bores 20,9 and bore 22,23 and 24,25 of extension member 2 and nail 1. The positioning leg 33 has bore 38 corresponding to bore 20 in the extension. Marino further discloses drilling guide 32 comprises a tubular positioning leg 33 shaped and dimensioned to engage into the proximal end 8 of the extension 2. It should be noted that the positioning leg 33 is not threaded but fits snugly into the extension 2.(Marino Col 3 . line 15-22) A bifurcated lower tip 34 engages the sleeve 10 with the upper end 35 of the forked tip 34 coming to rest against the upper edge of the sleeve 10. In that position any rotational movement of the guide 32 in relation to the extension 2 is prevented. Applicant discloses structure of connecting end of targeting device and connecting end of intramedullary nail coupled or mounted by threaded connecting bolt for better fitting for accuracy of targeting jig.

Fig. 2

Applicant points out that as disclosed by Marino (Fig. 1,5 and 6) positioning leg 33 is also drilled with bore 38 corresponding to the position of bore 20 in the extension and the second pin 21, looking to Fig 2, 5 and 6 after targeting bore 20 in extension member 2 through bore 38 in positioning leg 33 and fixing it with suitable anchor or screw , bifurcate arms of positioning leg 33 will be firmly fixed with extension member and will not allow disengagement of targeting jig from extension member after surgery is complete or one has to engage screw or anchor through bore 20 of extension 2 drilling bone free hand without targeting guide which leads to invasion to patient failing the purpose of surgery. Applicant further points out that Marino discloses structure of Guide arm 37 having a) proximal bores 38 and 39 for corresponding holes 20 and 9 in extension member 2 and b) distal bores 40 and 41 for corresponding holes 22, 23 in extension member 2 , bores 24 ,25 in proximal part of nail member 1 and holes 31 in side plate 19, where proximal bores 38 and 39 and distal bores 40 and 41 are in same plane or parallel plane (Fig. 5 and 6.) With the use of kit disclosed by Marino similar apparatus having structure of proximal holes and distal holes in same plane or parallel plane , surgeon has three undesired possibilities (problems), first possibility is to have reduction of fracture and alignment of head and neck fragment with shaft in one plane

that is non anatomical and fix the fracture in that position which is not desirable, second possibility is to have desired anatomical reduction and have engagement of proximal hip pins in midsection of head and neck of femur in desired position by rotating jig and nail mounted thereof leading to alignment of distal holes in jig and nail in odd position to fix with fear of damaging vital structure like vessel or nerve while drilling and abandoning the distal locking screw leading to rotationally insecure fixation of assembly and possible undesired outcome of loss of fixation and third possibility is to have desired anatomical reduction and have engagement of distal locking screws in midsection of shaft of femur bone and have engagement of proximal hip pins in head and neck eccentrically leading to very high possibility of failure of fixation by cut through of hip pins from head and neck- commonest complication and undesired event. So kit of Marino or similar described in prior art does not provide fixation of proximal hip pins (through proximal holes in nail) in midsection of head and neck portion of femur bone and simultaneously allow fixation of distal locking screws (through distal holes in nail) in midsection of shaft of femur bone with anatomical reduction of fracture leading to desirable outcome.

Present invention overcomes the above mentioned drawbacks found in the Marino or other like apparatus common in prior art by providing structure and construction of a first plurality of proximal holes and first plurality of distal holes in intramedullary nail along with corresponding second plurality of proximal holes and second plurality of distal holes in targeting device such that plane of center of a first plurality of proximal holes in intramedullary nail is extending to midsection of head and neck portion of femur bone and is intersecting (not parallel) with plane of center of first plurality of distal holes of intramedullary nail extending through midsection of shaft of femur such that a plurality of proximal hip pins is engagable in midsection of head and neck portion through a first plurality of proximal holes slidably and simultaneously a plurality of locking screw is engagable in midsection of shaft of femur through a first plurality of distal holes without rotating a targeting device with intramedullary nail connected therewith. (Present application Para[[0005],[0016],[00028],[00040],[00086],[00087],[00096], **Figs. , 9, 28 and 31 shown below.**).



The structural combination of elements set forth in the present **claim 1 and 28**, as well as the manner, in which that structural combination of elements is used, is distinctly different from that disclosed in Marino and subject matter of claim 1 and 28 of present invention is neither anticipated nor rendered obvious by the reference. For claim 27 and Claim 28 replacing Judet's side plate with shouldered plurality of barrels in place of Marino's side plate does not provide solutions to deficiency of Kit of Marino. For example for inserting a plurality of angled barrel member with side plate as disclosed by Marino and Judet requires large incision by open method and tissue dissection of lateral cortex which is already broken very badly having less blood supply from soft tissue and will require large diameter drilling for plurality of angled barrel member 18 which will lead to further weakening of lateral cortex of femur bone which is already broken very badly and further hampering platform for controlled collapse of fracture gap,

which teaches away from applicant's disclosure of minimal invasiveness. Applicant points out that with applicant's invention, buttress plate 50 having narrow obtuse end 84 is slid on surface of greater trochanter 3 and lateral cortex 22 of femur from first small incision at tip of greater trochanter 3 and structure of slit 86 helps in positioning of buttress plate on guide pins at second small incision at lateral cortex 22 without much soft tissue dissection (Present application para [00093],[00096], Figs 24,25). Applicant respectfully argues that Kit provided by Marino has composite fixation pin 11 to engage head and neck of femur through angled barrel member 18 of plate 19 across through bore 9 in extension member 1 and now according to combination of Judet with Marino one more barrel member is accommodated across through bore 20 of extension member of Marino requiring to enlarge that small hole 20 in extension member leading to further weakening of nail wall of extension member and creating stress riser and in turn one has to increase diameter of extension member 2 to overcome weakness of wall of extension member 2 leading to either difficult and forceful insertion of large diameter nail in medullary canal or to have option of enlarging the medullary canal by more reaming and invasion to bony tissue which is already deficient in old age patients having generally fracture in this area of junction of head-neck and shaft of femur. Applicant discloses contrarily to that barrel members 51 not across through (Present Application Fig. 21 and 30) the proximal holes 37 of intramedullary nail 42 to keep diameter of head part 43 intramedullary nail 42 smaller to avoid more reaming of bony tissue and to avoid much force for insertion leading to minimal invasion to patient . Present invention disclosed by applicant provides even distribution of forces due to structure and construction of planes of proximal holes and distal holes intersecting with each other, providing dynamic mechanical fixation with unitary nail having strength with precision and minimal invasion to patient. Marino does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at independent claim 1 or 27 or 28 of present invention. . So applicant respectfully argues that applicant's invention as a whole structurally and functionally different from disclosed Marino's kit and even on application of teachings of Judet side plate on Marino's kit does not yield predictable and improved results leading to improved resultant assembly and also modification of Marino's kit in view of side plate of Judet or combining teachings of references does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at

independent claim 28 or dependent claim 27 of present invention. Applicant respectfully further argues that Engelhardt et al US 4,805,607 discloses a modular two piece intramedullary nail 20 comprised of two major components , namely an elongated base nail 22(Col.3 ll 50 – Col. 4 ll 1-35, Figs. 2-3) and an extension member 24 intended for elective attachment to one end of base nail by a complex joint. The modular intramedullary nail 20 comprising base member is intended for the repair of long bone fractures, most notably femur and tibia and further described that, the base nail 22 is intended for placement in medullary canal of long bone like femur and preferably curved to a radius of approximately 60 to 80 inches. Engelhardt et al further teaches that mid region of base nail 22 has very deeply fluted or tri-flanged cross section shape and an extreme tip 28 of base nail at its leading end is moderately blunt, displaying a radius , for example , of approximately 0.125 inches, at trailing end of base nail 22 , the flanges 26 are faired into cylindrical bearing region 32 and a pair of generally parallel , spaced apart, engagement tongs 34 extending away from bearing region 32 and are resilient in directions toward and away from each other for locking with extension member. Applicant respectfully argue that the structure of nail having base member 22 here is intended to be placed into hollow medullary cavity as opposite to applicant's intention to use such hip pin in cancellous dense packed bone of head and neck of femur bone which is *not modular* or has *no curvature* and it has sliding surface and fixed slidably through the a first plurality of holes of intramedullary nail, a plurality of barrels and central large holes of buttress plate and it has at its trailing end no element of structure for locking with any extension member and at leading end it has triflanged surface and not at mid region. Applicant further argues that base nail 22 as taught by Engelhardt et al having deeply fluted or triflanged cross section will lead to more loss of metal from nail and weakening and increase the possibilities of breakage as nail placed in medullary canal of long bone like femur is subjected to more forces than compact dense bone of head and neck portion of femur bone. Intramedullary nail disclosed by Engelhard et al have same disadvantages as Marino's Kit. Modification of Marino's kit in view of Intramedullary Nail of Engelhard et al or combining teachings of references does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at Independent claim 28 or dependent claim 27 of present invention. Applicant further argues that Middleton claims a in situ formed anchor where it is essential to form a pilot hole in the bone having first

diameter and forming a cavity in bone connected with pilot hole and distal to pilot hole having second diameter which is substantially larger than first diameter and also requires to have performed implant element having holes as interlocking elements wherein there is substantial space between interlocking elements and boundary of said cavity, injecting a hardenable material into cavity to make insitu formed anchor to hold bone. Applicant points out that in situ anchor provided by Middleton is not the same as fixation assembly as described and claimed by applicant in amended claim 24. For example, with Applicant's claimed invention, proximal hip pin comprising triflanged part with multiple holes is specifically in direct contact with cancellous bone and not within any bone cavity that means there is no any substantial space between the triflanged part with multiple holes and bony tissue of head and neck of femur. This is not taught by Middleton. Middleton does teach to form a cavity surgically with the help of cavitations devices before placing anchoring implant in bone and teaches to have substantial space between placed implant and boundary of cavity where placed anchoring implant is not in direct contact with bony tissue, which is contrarily to Applicant's teaching. Making a cavitations in bone having substantially large diameter than the shaft or body of screw and filling this large cavity with cement or any harden able material has drawbacks of further weakening the bone and necrosis due to exothermic reaction to large amounts of such artificial material and it does not allow to have more than one anchors in head and neck of femur which is many a times essential to have for rotational stability and better fixation in osteoporotic bone in elderly , Applicant further points out that having substantially large cavity and having space between performed element and cavity boundary , in cases where cavity is filled only partially there will be no full bondage between performed anchoring element and bone leading to loss of fixation and there will not be any second chance to improve the fixation. Together with arguments and the reasons set forth above, Applicant herewith has shown that Middleton does not make obvious applicants invention. Applicant respectfully requests rejection of claim under USC 103 (a) be removed.

Conclusion

Consideration for and allowance of the pending claims in this Application, as provided in the Listing of Claims beginning on page three of this paper are respectfully requested for the reasons set forth herein. In light of amendments, remarks and arguments presented with this paper, Applicant respectfully submit that the pending and amended claims are in condition for allowance. No new matter has been introduced with this Amendment.

This amendment is timely filed with request for extension of time under CFR 1.136 with appropriate fees. No additional fees are believed due with this response. If this is incorrect, the Commissioner is authorized to charge such fees, other than the issue fee, that may be required by this paper to Deposit Account No: 20-0674.

If the Examiner has any question or comments or if further clarification is required, it is requested that the Examiner contact the undersigned pro se inventor at the telephone number: +91 9825387016.

Respectfully submitted,

Date: November 01, 2009

/Navin N Thakkar/

Signature

Printed Name: Navin N Thakkar

Pro Se Inventor

Customer Number: 86798(recently allotted)